

WHAT IS CLAIMED IS:

1. A method of preparing a mixed formulation of sustained release microspheres by a continuous one-step process, comprising:

5 preparing two to four different fluids for preparation of the sustained release microspheres containing a biodegradable polymer and a peptide drug; and

continuously supplying the mixed fluids from the two to four different fluids to a dryer via a single spray nozzle by controlling the mixing ratios of the fluids according to the time to dry the fluids.

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2. The method as set forth in claim 1, wherein the fluids contains the biodegradable polymer, the peptide drug, an additive and a solvent with different compositions of one or more of the components.

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3. The method as set forth in claim 1, wherein the sprayed fluids are dried by a spray-drying method, a spray freeze-drying method, or a supercritical fluid-based drying method.

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4. The method as set forth in claim 1, further comprising dispersing the sustained release microspheres in a solution containing a dispersion excipient and freeze-drying a resulting solution.

5. The method as set forth in claim 1, wherein the peptide drug is selected from among peptides of 2 to 60 amino acid residues in length and salts thereof.

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6. The method as set forth in claim 5, wherein the peptide drug is selected from among luteinizing hormone releasing hormone (LHRH) analogs, octreotide and salts thereof.

5 7. The method as set forth in claim 6, wherein the LHRH analogs are selected from among triptorelin, leuprolide, goserelin, nafarelin, buserelin, histrelin and salts thereof.

8. The method as set forth in claim 1, wherein the biodegradable polymer is selected
10 from polylactide, polyglycolide, poly(lactide-co-glycolide), polyorthoesters, polyanhydrides, polyamino acids, polyhydroxybutyric acid, polycaprolactone, polyalkylcarbonate, lipids, fatty acids, waxes, and derivatives and mixtures thereof.

9. The method as set forth in claim 8, wherein the biodegradable polymer is selected
15 from polylactide and poly(lactide-co-glycolide).